

Title: Changes in diversion rates following the introduction of a reformulated

extended release oxycodone product

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Abstract:

<u>Study Objectives</u>: In August 2010, a reformulation of OxyContin® (oxycodone HCl controlled-release) tablets was introduced, which is intended to be more difficult to crush and forms a gel when dissolved, with the aim of deterring abuse. It is hypothesized that the introduction of the reformulation would lead to decreased diversion of OxyContin through illegal channels due to reduction in demand for abuse. This study examines whether there was a decline in rates of diversion of OxyContin following the introduction of reformulated OxyContin (ORF) using data collected from drug diversion agents participating in the RADARS® System, an established surveillance system for prescription drug abuse. Other prescription opioids were used as a comparator.

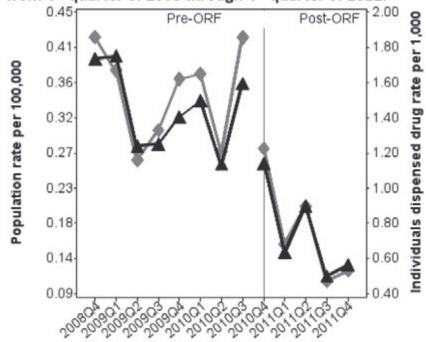
<u>Methods</u>: Diversion cases were obtained on a quarterly basis from law enforcement agencies. The Diversion Program surveyed 300 reporters in 50 states, covering 45% of the US population in the 4th quarter of 2011. Diversion rates per 100,000 population and per 1,000 unique recipients of dispensed drug (URDD) were calculated for each quarter. October 1, 2008 through September 30, 2010 was considered the period before and October 1, 2010 to December 31, 2011 the period after introduction of ORF. The mean rate of drug diversion was compared before and after the introduction of ORF for OxyContin and other prescription opioids using negative binomial regression. The data used from this program did not distinguish between original OxyContin and ORF in the post-ORF period.

Results: There was a 50% decline (95% CI: 24-67%) in the OxyContin diversion population rate from 0.34 per 100,000 before to 0.17 per 100,000 after the introduction of ORF. There was a 48% decline (95% CI: 24-64%) in the OxyContin diversion URDD rate from 1.43 to 0.75 per 1,000 URDD before versus after introduction of ORF. These changes were greater than those observed for other opioids across these same time periods (6% decline in population rate and 14% decline in URDD rate).

<u>Conclusion</u>: These findings indicate that the introduction of the reformulation was followed by a decline in diversion of OxyContin which was significantly greater than that observed for other prescription opioids. The decreased diversion of OxyContin to illegal channels suggests a decline in demand for the reformulation versus the original formulation.

Figure on next page

Diversion rates per 100,000 population and 1,000 individuals dispensed drug for OxyContin® from 4th quarter of 2008 through 4th quarter of 2011.



OxyContin® - Population rates



OxyContin® - Individuals dispensed drug rates

